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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. US BIOSERVICES, CORP., Defendant.	:	17 Civ. _____ **COMPLAINT**

The United States, by its attorney, Joon H. Kim, the Acting United States Attorney for the Southern District of New York, alleges for its complaint as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by the United States (the "Government") against US Bioservices Corp. ("US Bio") under the False Claims Act (the "FCA"), 31 U.S.C. § 3729 *et seq.*, to recover treble damages sustained by, and civil penalties and restitution owed to, the Government as result of US Bio's participation, from August 2010 until March 2012, in a kickback relationship with Novartis Pharmaceuticals Corp. ("Novartis") in relation to Exjade, an iron chelation drug manufactured and marketed by Novartis.[1]

[1] The Government previously sued, and settled with, the other three participants in this kickback scheme — Novartis, Accredo Health Group ("Accredo"), and BioScrip Inc. *See United States* ex rel. *Kester v. Novartis Pharm. Corp.*, et al., 11 Civ. 8196 (CM), Dkts. 41, 418, 540 (settlement stipulations with BioScrip, Accredo, and Novartis, respectively).

2. As discussed below, US Bio agreed to participate in an arrangement with Novartis under which US Bio could receive additional patient referrals and related benefits in return for achieving a higher refill rate than the other two pharmacies in the exclusive distribution network for Exjade. Specifically, to increase the refill rate, US Bio had its nurses and other staff call patients to recommend that they order refills of their Exjade prescriptions.

3. The federal anti-kickback statute (the "AKS"), 42 U.S.C. § 1320a-7b(b), expressly prohibits any entity or individual from, *inter alia*, soliciting or receiving any "remuneration," *i.e.*, anything of value, "in return for … recommending purchasing [] or ordering" a drug or service that is covered by federal healthcare programs like Medicare or Medicaid. *Id*. § 1320a-7b(b)(1). In 1994, as relevant here, the Government issued public guidance explaining that pharmacies like US Bio could violate the AKS by soliciting or receiving benefits "in exchange for performing marketing tasks in the course of pharmacy practice," including "sales-oriented 'educational' or 'counseling contacts'" or "patient outreach." *See* 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

4. Although US Bio knew that the AKS prohibited it from soliciting or receiving remuneration to recommend Exjade refills to patients, it disregarded that prohibition. Instead, US Bio acquiesced to pressure from Novartis and agreed to participate in a kickback arrangement under which it would compete for patient referrals – which Novartis controlled – against the other two specialty pharmacies that were distributing Exjade based on which pharmacy achieved the highest refill rate. *See infra* ¶¶ 44-63.

5. As part of this arrangement, US Bio sought to increase the refill rate among its Exjade patients in two ways. First, US Bio had nurses contact Exjade patients and offer one-sided advice that highlighted the importance of taking Exjade and downplayed the potential

adverse effects. More specifically, US Bio trained its nurses to call and tell Exjade patients that not treating iron overload, for which Exjade is prescribed, could have severe consequences like organ failure, and that while Exjade had certain common side effects like diarrhea, such side effects typically went away with time. Second, US Bio also assigned a group of patient care coordinators ("PCCs") to call Exjade patients and encourage them to order refills. In this regard, US Bio assigned budgeted goals to the PCCs in terms of the number of Exjade refill orders they should aim to obtain. *See infra* ¶¶ 49-53.

6. By agreeing to participate in this kickback arrangement, US Bio competed for access to Exjade patient referrals and earned hundreds of thousands of dollars each year in service fees and rebates. Government programs like Medicare and Medicaid, on the other hand, paid millions of dollars for Exjade shipments based on false claims submitted by US Bio that were never entitled to federal reimbursement. *See infra* ¶¶ 61-63.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over the Government's claims under the FCA pursuant to 28 U.S.C §§ 1331 and 1345.

8. This Court may exercise personal jurisdiction over US Bio. Further, because US Bio transacts business in this District and, in furtherance of the fraudulent kickback scheme, submitted and/or conspired to submit false claims in this District, venue is proper in this District pursuant to 31 U.S.C. § 3732(a) as well as 28 U.S.C. §§ 1391(b) and 1391(c).

THE PARTIES

9. Plaintiff is the United States of America. Through its agency the United States Department of Health and Human Services ("HHS"), the Government administers the Medicare and Medicaid programs.

10. Defendant US Bio is a specialty pharmacy and, during all relevant times, had its principal place of business in Addison, Texas.

THE APPLICABLE STATUTES – THE AKS AND THE FCA

11. The AKS, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration given to those who can influence health care decisions would result in the provision of goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect patient and federal healthcare programs, including Medicare and Medicaid, from these harms, Congress enacted in 1972 a prohibition against the payment of kickbacks in any form. In 1977 and 1987, Congress strengthened the statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Publ. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Publ. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

12. The AKS makes it illegal for individuals or entities to "solicit[] or receive [] any remuneration (including any kickback, bribe, or rebate) . . . in return for purchasing, ordering . . . or recommending purchasing [] or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1). Receipt of remuneration by a pharmacy from a drug company in return for recommending the company's drug violate this statute to the extent that the drug is reimbursed by a federal health care program. Violation of the AKS is a felony punishable by fines and imprisonment, and also can result in exclusion from participation in federal health care programs. *Id*.; *see also* 42 U.S.C. § 1320a-7(b)(7).

13. As early as 1994, the Government made it clear that the AKS prohibits improper

relationships between pharmacies and drug manufacturers designed to incentivize the pharmacies to help the manufacturers market their drugs to patients or physicians. Specifically, HHS-OIG issued "Special Fraud Alerts" in December 1994 explaining that a drug company "offer[ing] cash or other benefits" to pharmacies "in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid," including, specifically, "sales-oriented 'educational' or 'counseling' contacts … or patient outreach" raised AKS concerns. *See* 59 Fed. Reg. at 65,376 (Dec. 19, 1994).

14. In addition, to provide guidance on the AKS, HHS-OIG also has offered interested parties the opportunity to seek "formal advisory opinions" regarding, *inter alia*, the application of the AKS and the AKS safe harbor regulations to any existing or proposed business arrangement. *See generally* 42 C.F.R. Part 1008.

15. The FCA reflects Congress's objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. No. 99-345, at 1 (1986). As relevant here, the FCA establishes treble damages liability to the United States for an individual or entity that:

> (i) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A);
>
> (ii) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, *id*. § 3729(a)(1)(B); or
>
> (iii) "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid," *id*. § 3729(a)(1)(C).

"Knowing," within the meaning of the FCA, is defined to include reckless disregard and deliberate indifference. *Id*. In addition to treble damages, the FCA also provides for assessment

of a civil penalty for each violation or each false claim.[2]

16. The Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119, amended the AKS by expressly providing that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

THE FEDERAL HEALTH CARE PROGRAMS

17. ***Medicare Part D***. Medicare is a federal program that provides federally subsidized health insurance for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq*. ("Medicare Program"). As relevant here, Part D of Medicare, which was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, provides prescription drug benefits for Medicare beneficiaries. All persons enrolled in Medicare Parts A or B are eligible to enroll in a prescription drug plan under Part D.

18. Under Medicare Part D, HHS, through its component the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. The Part D sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors, in turn, subcontract with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

19. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to that Part D beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through a pharmacy benefit manager, or "PBM"). The

[2] Under the FCA, as adjusted by applicable federal laws and regulations, civil penalties for violations occurring between September 29, 1999, and November 1, 2015, such as those alleged here, are $5,500 to $11,000. *See* 28 U.S.C. § 2461 (notes); 64 Fed. Reg. 47,099, 47,103 (1999),

pharmacy receives reimbursement from the Part D sponsor (or the PBM) for the portion of the drug cost not paid by the beneficiary.

20. The Part D sponsor then is required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and whether the drug is covered under Medicare Part D. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program. Submitting PDE claims data to CMS, which is necessary for CMS to administer the Part D program and make payments to Part D sponsors for qualified drug coverage, is a condition of payment for CMS's provision of Medicare funds to Part D sponsors. *See* 42 C.F.R. § 423.322.

21. Under Medicare Part D, CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. *See* 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS then reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data submitted by the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS determines that it underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference; and if CMS determines that it overpaid the sponsor, it will

recoup the overpayment from the Part D sponsor.[3] The payments made by CMS to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

22. In order to receive Part D funds from CMS, the Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions. By statute, all contracts between a Part D sponsor and HHS must include a provision whereby the sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112. Further, CMS regulations expressly require Part D sponsors to certify, in their contracts with CMS, that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. *See* 42 C.F.R. § 423.505(h)(1).

23. Accordingly, all contracts entered into between CMS and Plan D sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729*, et seq.*), and the anti-kickback statute (§ 1127B(b)) of the Act." Further, CMS regulations also expressly require that all subcontracts between Part D sponsors and downstream entities – including pharmacies – contain language obligating the pharmacies to comply with all applicable federal laws, regulations, and CMS instructions. *See* 42 C.F.R. § 423.505(i)(4)(iv).

[3] After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. *See* 42 C.F.R. § 423.336.

24. CMS regulation further requires Part D sponsors to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.
>
> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. . . .

42 C.F.R. § 423.505(k). Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under the Medicare Part D program to the extent that it involves a violation of the AKS.

25. In accordance with this regulatory requirement, since the Part D program began, CMS has required each Part D sponsor to sign annually an Attestation of Data Relating to CMS

Payment to a Medicare Part D Sponsor ("Attestation"), which states:

> Pursuant to the contract(s) between the [CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D

> Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

All approved Part D sponsors who received payment under Medicare Part D after 2006 submitted these required Attestations in the same or similar format.

26. Finally, with regard to pharmacies and other subcontractors participating in the Part D program, CMS regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

27. ***Medicaid***. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. *See* 42 U.S.C. § 1396d(b). Among the states, FMAP is at least 50 percent and as high as 83 percent.

28. The Medicaid programs in all states reimburse for prescription drugs. Under the Medicaid Drug Rebate Statute, 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1), and in exchange for Medicaid coverage for their drugs, drug manufacturers like Novartis enter into national rebate agreements that require them to pay rebates to state Medicaid programs when their drugs are dispensed to Medicaid patients. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state

Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). *See* 42 C.F.R. § 430.30.

29. Claims tainted by illegal kickbacks are not authorized to be paid by Medicaid. First, Medicaid, like Medicare, is a federal healthcare program, and compliance with the AKS is a condition of payment for Medicaid claims. Second, most states have promulgated their own statutes or regulations against kickback relationships in connection with the provision of any services covered by Medicaid. For example, during the relevant time period, New York's Medicaid statutes expressly made it a crime for a Medicaid provider to "solicit, receive, accept or agree to receive or accept" or "offer, agree to give, or give any payment or other consideration in any form to another person to the extent such payment or other consideration is given … to purchase [] or order any good … or item" covered by Medicaid. N.Y. Soc. Serv. L. § 366-d(2); *see also* 18 N.Y.C.R.R. § 515.2(b)(5) (defining kickback relationships as a type of "unacceptable practice" for purposes of Medicaid).

30. Further, providers participating in the Medicaid program have been required to sign enrollment agreements with their states certifying compliance with the state and federal Medicaid requirements, including the AKS. Although there have been variations among the states, the agreement typically has required the prospective Medicaid provider to agree that he or

she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished. Indeed, in many states, Medicaid providers, including both physicians and pharmacies, affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations. In New York, for example, physicians and pharmacies have been required to periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished," "will be subject to the following certification. . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

31. Finally, state regulatory regimes also have conditioned payment of Medicaid claims on compliance with the AKS and/or the comparable state law provisions. For example, the New York regulatory regime has provided that an "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake." N.Y.C.R.R. Title 18 § 518.1(c). "Unacceptable practice" has been defined to include "soliciting or receiving" any "[b]ribes and kickbacks," in "return for … recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program." *Id.* § 515.2(b)(5). New York's anti-kickback statute forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law § 366–d(2). During the relevant times, similar statutory, regulatory, and program requirements existed in at least twenty-six other states (in addition to New York) and

the District of Columbia.[4]

US BIO'S PARTICIPATION IN THE EXJADE KICKBACK ARRANGEMENT[5]

I. Exjade's Launch and the Exclusive Distribution System for Exjade

32. In November 2005, Novartis sought and obtained accelerated approval from the Food and Drug Administration ("FDA") to market Exjade for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older.

33. Exjade was marketed for use by a small patient population having chronic iron overload due to blood transfusions. These patients had received blood transfusions in connection with several types of serious underlying conditions, including myelodysplastic syndromes ("MDS"), beta thalassemia, and adult and pediatric sickle cell disease ("SCD").

34. When it launched Exjade in 2005, Novartis also created an exclusive network called EPASS ("Exjade Patient Assistance and Support Services") to distribute the drug. EPASS consisted of just three specialty pharmacies — US Bio, Accredo, and BioScrip (collectively, the "EPASS SPs").

35. To be accepted as a member of EPASS, US Bio submitted a bid to Novartis that detailed, among other things, whether US Bio was authorized to serve Medicaid patients in vaious states. US Bio provided this information in its application because both it and Novartis knew that Medicaid would be a key source of coverage for Exjade dispensed by US Bio. Further, because many MDS patients are elderly, US Bio and Novartis also expected Medicare Part D to

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[4] The additional jurisdictions are: Arizona, California, Colorado, Connecticut, District of Columbia, Florida, Illinois, Indiana, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, Nevada, Oklahoma, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Virginia, Washington, West Virginia, and Wisconsin.

[5] While the claims asserted against US Bio in this case arise from conduct that occurred between August 2010 and March 2012, this Complaint discusses facts relating to the full duration of US Bio's Exjade relationship with Novartis, *i.e.*, from 2005 to March 2012.

be a major source of coverage for Exjade that US Bio would dispense.

36. Under EPASS, doctors who wished to prescribe Exjade would submit a patient registration form and the prescription to the EPASS system for fulfillment. EPASS then distributed those prescriptions among the three EPASS SPs. More specifically, certain Exjade prescriptions were directed to a particular EPASS SP based on insurance requirements or physician preference. The remaining prescriptions (the "undesignated patient referrals") – consisting of about half of all Exjade prescriptions – were not designated for a particular EPASS SP by insurers or physicians, but instead were assigned among the EPASS SPs as directed by Novartis.

37. Within EPASS, Novartis controlled the distribution of the undesignated patient referrals among the three EPASS SPs. In this regard, US Bio and Novartis understood that getting more undesignated patient referrals was economically valuable for US Bio — having more Exjade patients led to higher sales revenue, more dispensing fees, and additional rebates.

38. In December 2005, US Bio signed a contract with Novartis to distribute Exjade as an EPASS SP. US Bio and Novartis expected that nearly 100% of the Exjade that US Bio dispensed to patients would be shipped by mail. Payor rules as well as US Bio's internal procedures required US Bio to obtain patient consent before it could send an initial Exjade shipment or a refill to the patient.

II. Updates to Exjade's Safety Profile

39. Upon Exjade's launch in 2005, the package insert (commonly referred to as the "Exjade Label") indicated the most common adverse events included vomiting, nausea, abdominal pain, and an increase in serum creatinine (a clinical measure of kidney function).

40. Pursuant to FDA's regulations for accelerated approvals, Novartis was required

to submit all Exjade promotional materials to FDA for review. As part of that review process, the FDA advised Novartis in 2005 and 2006 that Exjade promotional materials should not imply that Exjade had been shown to be effective for preventing multi-organ damage and also should indicate that further studies were being performed to determine whether taking Exjade provided long-term benefits and/or presented long-term risks.

41. As a condition of its participation in EPASS, US Bio agreed to collect data regarding the reasons that Exjade patients stopped ordering refills and send that data to Novartis through the EPASS system. By 2007, the discontinuation data that US Bio and the other EPASS SPs collected showed that physicians' choices to discontinue Exjade and the side effects of Exjade therapy were common reasons reported by Exjade patients for not ordering refills.

42. In the meantime, post-approval safety studies showed that the adverse reactions associated with Exjade use were more severe than indicated in the original Exjade Label, leading to a series of updates that added numerous warnings, including:

- In late 2006, the Exjade Label was updated to indicate that kidney failures and cytopenias (a reduction in production of certain blood cells) had been reported.
- In April 2007, the Exjade Label was updated to report that some patients with kidney failure and cytopenias had died.
- In January 2008, a clinical recommendation was added to the Exjade Label, emphasizing to prescribers that prescribing Exjade to patients to remove iron should be based on the anticipated "clinical benefit and risks of Exjade therapy." In addition, the updated Exjade Label also included a warning about liver failures.
- In October 2008, two more warnings were added to the Exjade Label — one regarding gastrointestinal ulcerations and bleeding, and the other regarding Exjade's toxicity at higher doses for patients with lower blood iron levels.

Those updates culminated in 2010 with the requirement that the Exjade Label feature a "Black

Box warning."[6]

43. The January 2010 "Black Box warning" highlighted the fact that "Exjade may cause" kidney failure, liver failure, and gastrointestinal hemorrhage, which were fatal in some reported cases. The revision to the Exjade Label also specified that Exjade was contraindicated for patients with "high-risk MDS," *i.e.*, MDS patients who are sicker than other MDS patients.

III. In Late 2007, US Bio Agreed to Help Novartis Encourage Exjade Patients to Order Refills So That It Could Keep Receiving Undesignated Patient Referrals

44. Starting in late 2007, US Bio faced increasing pressure from Novartis marketing executives to increase the refill rates among US Bio's Exjade patients by assigning nurses to call Exjade patients and encourage them to stay on Exjade.

45. Specifically, in June 2007, US Bio, as well as the other two EPASS SPs, began receiving monthly "Exjade Scorecards" from Novartis that measured, among other things, the pharmacies' "adherence" scores. The "adherence" score in the Exjade Scorecards showed how long Exjade patients continued to order refills, without excluding patients who stopped ordering refills due to side effects or patients who were directed to stop therapy by their physicians.

46. Next, starting in July 2007, Novartis began admonishing US Bio that it needed increase its "adherence" score in the Exjade Scorecards. US Bio was told that, to increase Exjade refill rates, it needed to launch "a nurse program" whereby nurses would be assigned to call Exjade patients and discuss the benefits of Exjade treatment and how to manage side effects.

47. US Bio was also told that failing to improve its "adherence" score in the Exjade Scorecards could lead to the loss of patient referrals. Specifically, up to this time, the undesignated patient referrals had been distributed equally among the EPASS SPs according to a

[6] The "Black Box warning" is the strongest warning for a prescription drug that the FDA can require. Pursuant to FDA regulations, the warning must be in bold print and presented in a

"round-robin" system. But Novartis advised US Bio that this was likely to change — if US Bio did not increase its Exjade refill rates, then Novartis could assign fewer undesignated patient referrals to US Bio and instead give those patients to BioScrip and/or Accredo.

48. In late 2007, US Bio learned that, by launching a nurse program and increasing Exjade refill rates, it could be eligible to get a greater share of undesignated patient referrals than the other two EPASS SPs. For example, an associate marketing director at Novartis told the Exjade program manager at US Bio in a September 2007 conference call that Novartis was devising "a system by which the top performing [EPASS] SP would reap greater benefit[s]," including "additional [undesignated] patients."

49. In late 2007 and early 2008, in response to the pressure from Novartis, US Bio began training its nurses to call Exjade patients and tell the patients that not treating iron overload, for which Exjade is prescribed, could have severe consequences like organ failure, and that while Exjade had certain common side effects like diarrhea, such side effects typically went away with time.

50. For example, call notes kept by nurses at US Bio show the nurses told patients that they needed Exjade because it could protect them from harm to their "heart, pancreas, liver, joints, lungs, and reproductive organs." According to the nurses' calls notes, patients also were told that side effects associated with Exjade would "go away after a period of weeks."

51. Similarly, at a meeting in December 2007, the Exjade program manager at US Bio showed Novartis a sample discussion between a US Bio nurse and the parent of a pediatric SCD patient. According to that sample, the nurse told the parent that "it is important for [the child] to take his Exjade every day. Exjade is used to remove excess iron from the blood. A lot

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format that makes the information visually accessible. *See* 21 C.F.R. §§ 201.57(c)–(d).

of iron in the blood can cause [the child] to not grow as tall as he could and when he grows up, the iron in his blood could prevent him from having kids."

52. In addition to having nurses contact Exjade patients to encourage them to order refills, US Bio also assigned a group of PCCs to call Exjade patients to remind them to order refills. To incentivize the PCCs to generate more Exjade refill orders, US Bio assigned budgeted goals to the PCCs for the number of refill orders they should aim to obtain.

53. One way in which the PCCs at US Bio could get more refill orders was by enrolling Exjade patients in the "Autoship" program that US Bio operated. Once a patient was enrolled in that program, US Bio would automatically send an Exjade shipment to the patient every 28 days without having to confirm an order from the patient. In this regard, although US Bio's written policy prohibited the enrollment of patients in the "Autoship" program without express patient consent, managers at US Bio did not always enforce that policy when it came to Exjade. Thus, a number of Exjade patients were put into the "Autoship" program without their express consent.

IV. From October 2008 Until March 2012, US Bio Competed for Undesignated Patient Referrals Against Accredo and US Bio According to Exjade Refill Rates

54. In 2008, US Bio continued to engage in discussions with Novartis regarding how the share of undesignated patient referrals assigned to US Bio could be linked to the Exjade refill rates it achieved. In October 2008, those discussions culminated in US Bio's agreement to participate in a new scheme that Novartis had devised for allocating Exjade patient referrals among US Bio and the other two EPASS pharmacies, *i.e.*, Accredo and BioScrip.

55. Under this patient referral allocation scheme, 60% of all undesignated patient referrals would be given to the EPASS SP with the top "adherence" scores based on the Exjade Scorecards from the prior period, while each of the other two EPASS SPs would receive 20% of

the undesignated patient referrals. For example, in the first half of 2009, BioScrip received 60% of all undesignated patients because it had the highest adherence score in late 2008, while US Bio and Accredo each received 20% of such patients.

56. From 2008 to March 2012, US Bio also agreed to accept performance rebates from Novartis tied to whether the number of Exjade shipments US Bio dispensed each quarter met certain thresholds that Novartis set based on its internal Exjade sales targets.

57. Between October 2008 and March 2012,[7] US Bio knowingly participated in this patient referral allocation scheme by competing to get higher Exjade refill rates than Accredo and BioScrip so that it could receive more undesignated patient referrals. Specifically, US Bio continued to have its nurses and PCCs call Exjade patients to encourage them to order refills.

V. US Bio Knew That Its Participation in the Exjade Kickback Arrangement Was in Violation of the AKS

58. As a pharmacy taking part in the Medicare Part D and Medicaid programs, US Bio was required to – and did – represent that it would comply with the AKS and refrain from participating in kickback arrangements. *See supra* ¶¶ 17-31. But instead of honoring its representations and compliance obligation, US Bio knew that it was in violation of the AKS by virtue of its participation in the Exjade scheme.

59. Due to its awareness of the impropriety of this scheme, US Bio agreed with Novartis to conceal it from their written agreements. Specifically, while US Bio and Novartis amended their EPASS contract several times between 2008 and March 2012, none of the amended contracts described the agreement between US Bio and Novartis regarding the basis for

[7] In late March 2012, Novartis notified US Bio that, starting in April 2012, it would stop allocating additional Exjade patient referrals to the EPASS SP with the highest Exjade Scorecard ranking. The EPASS contract between US Bio and Novartis expired on March 31, 2012, and US

determining how many undesignated patient referrals US Bio would receive.

60. Further, US Bio allowed its interest in obtaining more Exjade refill orders – and thus getting more undesignated patient referrals – to override its own internal policies. For example, US Bio's policy forbade its employees from enrolling patients in the "Autoship" program without express consent. But PCCs knew that US Bio managers did not seriously enforce that policy when it came to Exjade because Autoship generated higher refill rates for Exjade. For example, US Bio managers learned that a PCC was repeatedly putting Exjade patients on Autoship without consent, yet the managers did not impose any serious discipline.

VI. US Bio Submitted Thousands of False Claims to Medicare Part D and Medicaid in Connection with Its Participation in the Exjade Kickback Arrangement

61. As explained above, *see supra* ¶¶ 17-31, during the relevant period, Medicare Part D and Medicaid prohibited the submission of claims by healthcare providers, like US Bio, that were tainted by kickbacks. US Bio, however, submitted thousands of claims to Medicare Part D and Medicaid between August 2010 and March 2012 for Exjade dispensed in connection with US Bio's participation in the kickback arrangement with Novartis. Those Medicare and Medicaid claims were false and ineligible for reimbursement because each claim was tainted by kickbacks.

62. Further, in seeking Medicare and Medicaid reimbursement, US Bio did not disclose its kickback relationship with Novartis or the fact that its Exjade claims resulted from a scheme that violated the AKS, a statute that US Bio was required to, and promised to, comply with under its contracts with Part D sponsors and Medicaid enrollment forms. US Bio also did not disclose that it was promoting Exjade refills in return for kickbacks from Novartis in the

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Bio and Novartis did not renew that contract. US Bio did not obtain 60% of the undesignated patient referrals between 2008 and 2012.

form of patient referrals and related benefits.

63. In connection with its participation in the Exjade kickback arrangement, US Bio earned hundreds of thousands of dollars each year in terms of service fees and rebates. The Government, on the other hand, paid out millions of dollars to reimburse US Bio for Medicare and Medicaid claims that were not entitled to payment.

FIRST CLAIM

Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

64. The Government incorporates by reference paragraphs 1 through 63 above as if fully set forth in this paragraph.

65. The Government seeks relief against US Bio under section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A) .

66. In connection with the Exjade kickback scheme, US Bio agreed to accept inducements from Novartis in the form patient referrals and associated benefits in return for recommending the purchasing or ordering of Exjade refills, in violation of the AKS, 42 U.S.C. § 1320a-7b(b), and presented claims for payment that were false or fraudulent to Medicare and Medicaid in violation of 31 U.S.C. § 3729(a)(1)(A).

67. By reason of the false or fraudulent claims presented to Medicare and Medicaid in connection with the Exjade kickback scheme involving US Bio and Novartis, the Government has been damaged in an amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements
(31 U.S.C. § 3729(a)(1)(B))

68. The Government incorporates by reference paragraphs 1 through 63 above as if fully set forth in this paragraph.

69. The Government seeks relief against US Bio under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

70. In connection with the Exjade kickback scheme, US Bio agreed to accept inducements from Novartis in the form of patient referrals and associated benefits in return for recommending the purchasing or ordering of Exjade refills, in violation of the AKS, 42 U.S.C. § 1320a-7b(b), and made false records or statements that were material to getting false or fraudulent claims paid by Medicare and Medicaid. Specifically, US Bio certified, stated, and/or represented that the payments it sought for Exjade shipments were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. These false certifications, statements, or representations, in turn, caused Medicare and Medicaid to pay out sums that would not have been paid if those programs had been made aware of the falsity of such certifications, statements, or representations.

71. By reason of these false records or statements used in connection with the Exjade kickback scheme involving US Bio, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

THIRD CLAIM

Violations of the False Claims Act: Conspiring to Violate the False Claims Act (31 U.S.C. § 3729 (a)(1)(C))

72. The Government incorporates by reference paragraphs 1 through 63 above as if fully set forth in this paragraph.

73. The Government seeks relief against US Bio under Section 3729(a)(1)(C) of the FCA, 31 U.S.C. § 3729 (a)(1)(C).

74. As set forth above, US Bio conspired with Novartis to orchestrate a kickback scheme in which US Bio agreed to accept kickbacks from Novartis in the form of patient referrals and associated benefits in exchange for recommending Exjade refills in violation of the AKS, 42 U.S.C. § 1320a-7b(b)(2), thereby causing US Bio to submit false and fraudulent claims to Medicare and Medicaid seeking payment for Exjade dispensed in connection with the scheme.

75. Accordingly, US Bio conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729 (a)(1)(C).

76. By reason of the conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B) involving US Bio and Exjade, the Government has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor as follows:

(a) On the First, Second, and Third Claims for relief (violations of the FCA, 31 U.S.C. §§ 3729(a)(1)(A), 3729(a)(1)(B), and 3729(a)(1)(C)), a judgment against US Bio for treble the Government's damages resulting

from US Bio's participation in the Exjade scheme, in an amount to be determined at trial, plus an $11,000 penalty for each false claim submitted in violation of the FCA;

(b) An award of costs incurred by the United States against defendant US Bio pursuant to 31 U.S.C. § 3729(a)(3); and

(c) such further relief as is proper.

Dated: New York, New York
August 22, 2017

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